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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	14

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/202,359	Arad
Examiner	**Group Art Unit**
David Lukton	1653

[X] Responsive to communication(s) filed on *Aug 15, 2000*

[ ] This action is **FINAL.**

[ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

[X] Claim(s) *1-17* is/are pending in the applicat

Of the above, claim(s) *1-7 and 9-11* is/are withdrawn from consideration

[ ] Claim(s) _____ is/are allowed.

[X] Claim(s) *8 and 12-17* is/are rejected.

[ ] Claim(s) _____ is/are objected to.

[ ] Claims _____ are subject to restriction or election requirement.

Application Papers

[ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

[ ] The drawing(s) filed on _____ is/are objected to by the Examiner.

[ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.

[ ] The specification is objected to by the Examiner.

[ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

[ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

[ ] All [ ] Some* [X] None of the CERTIFIED copies of the priority documents have been

[ ] received.

[ ] received in Application No. (Series Code/Serial Number) _____

[ ] received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

[ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

[X] Notice of References Cited, PTO-892

[ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

[ ] Interview Summary, PTO-413

[ ] Notice of Draftsperson's Patent Drawing Review, PTO-948

[ ] Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Pursuant to the directives of paper No. 13 (filed 8/15/00), claims 8 and 13-16 have been amended, and claim 17 added. Claims 1-17 remain pending, of which 1-7, 9-11 remain withdrawn from consideration. Claims 8 and 12-17 are examined in this Office action.

Applicants' arguments filed 8/15/00 have been considered and found persuasive. The previously imposed rejections are withdrawn herewith. However, new grounds of rejection are now imposed.

Applicants have sought clarification with regard to the restriction. Applicants' characterization of what the elected group encompasses appears to be correct. However, several additional groups (drawn to methods) are likely to be rejoined with the elected group. Claims drawn to compounds and compositions, however, will **not** be rejoined, and applicants are urged to cancel them.

*

This application contains at least one sequence disclosure that is encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the sequence on page 15, line 19.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result

in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

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The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 12-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown that several of the claimed compounds will inhibit picornavirus *in vitro*. However, while it may be stipulated that such inhibition will occur *in vivo* as well, treatment of a disease in a mammal is another matter. Successful treatment requires proper anatomical localization, and selective toxicity, in addition to other variables. Moreover, the inhibition would have to be sufficiently effective so that the population of virus in the host actually decreases. Inhibition without a decrease in population will not lead to a successful treatment. Enablement is lacking for the claimed invention.

However, applicants may amend the claims to recite either of the following:

A method of inhibiting picornaviral replication in a subject...

- or -

A method of inhibiting picornaviral 3C protease in a subject...

This amendment will be considered if **both** of the following conditions are met: (a) the foregoing method claims are introduced in response to this Office action, and (b) any and all claims drawn to treatment of a disease "caused by a picornavirus" are cancelled (or eliminated by amendment) in response to this Office action. In the event that applicants choose this option, the term "pharmaceutically" should be deleted at all occcurrences, since this implies therapeutic efficacy, which is not in evidence.

*

Claims 8 and 12-17 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the definition of R_1, part (i), claim 8 recites that R_1 can be a hydrocarbon chain of "about 1 [carbon atom]". With respect to this phrase, what is the smallest number of carbon atoms that would fall within the scope of the term "about 1 [carbon atom]"...? Would it include zero?. The term "about" should be eliminated at least when referring to one carbon atom.

Each of claims 8 and 17 recite that Y and Y' can be keto, sulfoxide or sulfone.

However, each of these functional groups must be bonded to two other groups; only one of these is accounted for. Is it the case that if e.g., "Y" is keto, that any alkyl, aryl or heteroaryl substituent can be bonded to the "keto" group...?

In claim 8, variable R_1 is defined in parts (i), (ii), and (iii). In part (iii), it is recited that R_1 can be "C_6-C_{10}-bicycloalkyl" or "C_3-C_7-cycloalkylmethyl". There should be a comma between each of these two Markush Group members.

In claim 8, Y and Y' are defined in parts (i), (ii), (iii) and (iv). In part (iii), it is stated that Y and Y' can be "C_1,-C_3 alkyl". Here, the comma following "C_1" is superfluous. See

Each of claims 13-16, the phrase "Z' and R^1 cannot form a ring" is superfluous, since none of these claims permit the ring anyway.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800